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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,245	04/04/2001	Thyge Borup Hjorth	6184.200-US	2682

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	8

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/826,245	HJORTH ET AL.
Examiner	Art Unit	
Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 September 2002 (paper no. 7) .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 26-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 26-48 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .

4) Interview Summary (PTO-413) Paper No(s). ____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the request for Extension of Time (3 months), the Amendment and the Information Disclosure Statement (IDS), all filed 09/27/02.

Upon careful review and consideration, the previous Office Action filed 03/27/02 has been withdrawn. The following are the new grounds for rejection:

Claims 26-48 are pending. Claims 1-25 have been cancelled. Claims 26-48 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is indefinite because the claim recites on lines 3-4, "and optionally a pharmaceutically acceptable carrier". The claim then recites on line 6, "and one or more pharmaceutically acceptable carriers". The claim is rendered indefinite since it is

unclear and confusing as to whether the pharmaceutically acceptable carrier is indeed an *optional* component in the composition or whether the pharmaceutically acceptable carrier *must be contained* in the composition. The claim is contradictory in nature since there is no reference point as to the requirement of the pharmaceutically acceptable carrier. Clarification is requested.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 contains the trademark/trade name "Tablettose 80" on page 5, line 3. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe *lactose monohydrate* and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 99/19313, collectively, "Lohray").

Lohray teaches a process for the preparation of (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid compounds, their pharmaceutically acceptable salts and pharmaceutical compounds containing them (see reference page 1, lines 1-22). The compound (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid has been found useful for the treatment and/or prophylaxis of

insulin resistance (type 2 diabetes), hypertension, hyperlipidemia, obesity, etc. (pg. 1, lines 24 through pg. 2, line25). The pharmaceutical composition may be in the form of tablets, capsules, powders, syrups, suspensions, solutions and the like and may contain flavorants, sweeteners, excipients and the like in suitable solid or liquid carriers or diluents, or in suitable sterile media to form injectable solutions or suspensions. Such compositions contain from 1 to 20% of the active compound and the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents (pg. 31, lines 14-20); (pg. 32, lines 2-16). Example 7 demonstrates a process for the preparation of ethyl 3-[4-[2-(phenoxyazin-10yl)ethoxy]phenyl]-2-ethoxypropanoate wherein three methods (A-C) are recited. Method A recites that to a solution ethyl (E/Z)-3-[4-[2-(phenoxyazin-10-yl)ethoxy]phenyl]-2-ethoxypropanoate obtained in example 3 in dioxane was added and stirred at 25° C under 60 psi hydrogen pressure for 24 h. At the end of this time, the reaction mixture was filtered and the solvent was evaporated under reduced pressure. Similarly, Examples B and C form a white solid product wherein Method C was a reaction mixture wherein water was added and extracted and organic extracts were washed with water, dried, filtered and evaporated.

The prior art teaches the same composition, method of use and a process for the preparation of a composition comprising the same compound (-) 3-[4-[2-phenoxyazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid as instantly claimed by the applicant (see claims 1 and 9). The prior art teaches such a composition comprising the same phenoxyazine compound wherein a pharmaceutically acceptable carrier, diluent,

excipient or solvate is included (claim 18). The composition can be in the form of a tablet, capsule, powder, syrup, solution or suspension (claim 19).

The instant claims differ from the reference of Lohray in that the instant claims have a limited scope. In actuality, the instant invention is a selection taken from the group of compounds taught by the prior art (Example 7 teaches the exact compound). The applicant is also attempting to differentiate from the prior art by claiming a compression technique in the process for preparation of the composition. However, compression techniques are well known to one of ordinary skill familiar with the pharmaceutical art for the formulation of tablets, capsules and the like.

Regarding the specified water content of the excipients, the water vapor pressure and the oxygen pressures, there is no criticality seen in the instantly claimed amounts or percentages, since the final end product of Lohray is a (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid compound in the form of a tablet, powder or capsule, etc as desired by the applicant. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Furthermore, in the absence of showing any unexpected results that accrue from the applicants claimed compound with excipients of a water content of below about 1%, one of ordinary skill in the art, could through routine or manipulative experimentation, obtain the best possible results.

Regarding the use of specified excipients as listed in applicant's claims 31-33 and 43-48, the examiner notes that these excipients are in fact, conventionally known

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excipients, readily used in pharmaceutical applications for the formulation of tablets, capsules and the like. As such, there is no showing of any unexpected results that accrues from the use of the specified excipients, as they are well known to one of ordinary skill in the art.

In conclusion, since Lohray et al. teach the same compound (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid, composition and a similar process for the preparation of a composition comprising (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid and the various forms of the compound (i.e., tablet, capsule, powder, etc.) (claims 18-19) as instantly claimed, one of ordinary skill in the art would have ample motivation to prepare such a composition comprising the same components for a similar intended purpose. The expected result would be a (-) 3-[4-[2-phenoxazin-10yl)ethoxy]phenyl]-2-ethoxypropanoic acid composition in solid form for the effective treatment and/or prophylaxis of insulin resistance (type 2 diabetes), hypertension, hyperlipidemia, obesity and various other cardiovascular, renal and related disorders.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


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